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2307U-107

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re application of<br>Robert L. Lundak<br>Serial No. 247,656<br>Filed: March 26, 1981<br>For: HIGH FUSION FREQUENCY FUSIBLE LYMPHOBLASTOID CELL LINE | Examiner: J. Tarcza<br>Art Unit: 172<br>PETITION UNDER 37 C.F.R. §1.181 |



San Francisco, CA 94105

Commissioner of Patents and Trademarks

Washington, D. C. 20231

Sir:

Applicant, by his attorney, hereby requests that the Honorable Commissioner exercise his supervisory authority and rule that on the following facts, the subject application fulfills the requirements for a deposit of a microorganism as provided for under M.P.E.P. 608.01(p) C. Deposit of Microorganisms. The reasons for this request are as follows:

(1) The law is unclear as to what is required for a deposit to obtain a filing date; and

(2) despite the ambiguity of the regulations, a good faith effort was made to deposit the microorganism on or before the date of filing, which deposit was, however, made two weeks after the filing date.

35 USC 112 states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Quite obviously, this language does not speak to deposits of organisms or for that matter anything other than a written description. Title 37 CFR 1.93 Specimens states:

> When the invention relates to a composition of matter, the applicant may be required to furnish specimens of the composition, or of its ingredients or intermediates, for the purpose of inspection or experiment.

It would appear from the statute and the Code of Federal Regulations that no deposit should be required, since the rules specifically provide for the PTO to request a composition of matter. I believe it does not require discussion to suggest that cells, plasmids, or other living organisms are compositions of matter. Diamond, Comr. Pats. v. Chakrabarty, 206 USPQ 193 (1980).

In 1970, a practice which was alleged to have been employed for 15 years was challenged in In re Argoudelis et al. The PTO rejected the deposit of an organism as fulfilling the enablement requirement of 35 USC 112. In In re Argoudelis et al., both the majority and concurring opinions, the primary emphasis concerns enablement as of the time of issuance of the patent application, not during the pendency of the application. The court stated, 168 USPQ, at 102:

> The disclosure is sufficient to permit a thorough examination by the Patent Office and to preclude the possibility that a patent could issue without any person skilled in the art being thenceforth enabled to make and use the invention.

Subsequently, 168 USPQ, at 103, the court stated:

> The only rational ground for concern on the part of the Patent Office appears to be for the permanent availability of the deposited micro-organism. The deposits are not a part of the patent application, and the Patent Office exercises no control over them. This concern may be justified in some situations. A similar problem was involved in In re Metcalf, 161 USPQ 789 * * * After considering the facts, the court concluded

> that the possibility that at some future date one skilled in the art may no longer be enabled to practice the invention was too speculative to justify a holding that the disclosure was insufficient under 112.

Subsequently, in Feldman v. Aunstrup, 186 USPQ 108 (CCPA 1975) the court almost, but not quite, reversed any requirement for having to deposit the microorganism prior to issuance of the patent application. The court specifically referred to the fact that the Office may request a specimen. Furthermore, the court stated, 186 USPQ, at 113:

> This is analogous to the complete public disclosure function of §112, first paragraph, and that function is only violated if the disclosure is not complete at the time it is made public, i.e., at the issue date.

In that case, the organism had been deposited in a private depository subject to the sole control of the patent applicant. Five years later during an interference, the private depository was requested to maintain the deposit in accordance with the rules of Argoudelis. Therefore, while applicant had separated possession from himself, applicant did not delegate control until long after the filing date of the application and provided for ensured maintenance after issuance of a patent only long after the filing date of the application. It should be further noted that the court in this instance was affirming the Board of Patent Interferences, where the Board of Patent Interferences was announcing the policy as to deposits of the PTO.

It would appear from the above discussion, that the rules concerning deposit are not clear and it is not certain that failure to deposit at the time of filing of the application precludes acceptance of the application, where the organism is deposited thereafter during pendency of the application or at the time the PTO requests deposit. Since

the court indicated that the M.P.E.P. 608.01(p) did not require deposit at the time of filing, but merely made this permissive, there has been substantial confusion as to what is required, so far as 35 USC 112 in relation to micro-organisms.

Since Argoudelis was concerned with naturally occurring microorganisms and not with the numerous different microorganisms which have been modified by hybrid DNA technology, the issue has become one of extreme importance. Furthermore, the much greater incidence of the production of microorganisms, the costs involved with deposit, and the greater possibilities for failure of communication, suggests that some flexibility in application of the deposit requirements is appropriate. The deposit requirement is not statutory and based on the Feldman and Argoudelis decisions is clearly an approach to a situation to attempt to achieve a certain goal. Nothing in the record of Argoudelis or Feldman supports the need for the Patent Office to have the deposit prior to issuance of the patent. The sole basis would appear to be the courts condoning the procedure as sufficient without analyzing whether the entire procedure was necessary.

There is the further consideration that under the applicable facts, the Commissioner is respectfully requested to employ his supervisory authority to reverse the Examiner's rejection of the subject application for failure to deposit the organism at the time of filing.

The following are the facts. On December 19, 1980, I received a letter from the Office of the Board of Patents of the University of California, with an enclosure, requesting me to provide an opinion on the patentability of

the subject invention. Such an opinion was provided and on January 7, 1981, I was authorized to begin preparation of the application. After discussions with the inventor, who was a Professor at the University of California, Riverside, on February 5, 1981, a disclosure was provided me for preparing the application. On February 24, 1981, a proposed application was forwarded to the inventor, requesting him to review the application, execute it if appropriate, return the executed application to me and to deposit the cell line at the A.T.C.C. The inventor promptly executed the application but withheld returning the application to me and requested his technician to grow up the cells so that they might be deposited.

On March 23, 1981, I forwarded the application to my associate in Arlington, Virginia and requested her to file the application upon my authorization, when I confirmed that the cell line had been deposited at the A.T.C.C. On or about March 26, 1981, I was informed by Dr. Lundak that the cell line had been forwarded to the A.T.C.C.and I notified my associate to file the application. In fact, the cell line had not been deposited and Dr. Lundak was under a misapprehension that the cell line had been forwarded. I became aware of this contretemps when I was informed by Ms. Brandon at the A.T.C.C., that I letter I had sent to her indicating that she had possession of the subject cell line was confusing, since she was unaware of such cell line. I promptly called Dr. Lundak and informed him of the situation. He investigated and found that in fact the cell line had not been sent and promptly corrected the situation. Therefore, there is a hiatus between the filing of the subject application which occurred on March 26, 1981 and the

deposit of the subject cell line which occurred on April 2, 1981.

Prior to and during the hiatus between the filing date and the deposit of the cell line, at all times Dr. Lundak had possession of the cell line and had deposited the cell line at a number of different sites to ensure the continued maintenance and availability of the cell line. As evidenced by the declaration which is of record, at no time was there any chance of the cell line being unavailable. Dr. Lundak not only maintained his own ampules, but as a further precaution, maintained ampules at the laboratories of Dr. Bruce Devens and Dr. Richard Lubin. In addition, the cell line was also stored at the laboratory of Dr. John Lewis, at the Loma Linda University Medical Center, Loma Linda, California. Therefore, the cell line was maintained at four different places by independent individuals, one of which characterized the cell line.

Based on the above facts, as well as the above law, it is submitted that the Honorable Commissioner should exercise his supervisory authority and reverse the Examiner's rejection under 35 USC 112 for failure of enablement due to the belated deposit of the cell line which is the subject matter of the subject application.

Respectfully submitted,

TOWNSEND and TOWNSEND

Date 5/5/83

By _____
Bertram I. Rowland
Reg. No. 20,015

BIR/gs
Attachments
1. Declaration of Rowland
2. Declaration of Lundak

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re application of | |
| Robert L. Lundak | Examiner: J. Tarcza |
| Serial No. 247,656 | Art Unit: 172 |
| Filed: March 26, 1981 | |
| For: HIGH FUSION FREQUENCY FUSIBLE LYMPHOBLASTOID CELL LINE | DECLARATION |

San Francisco, CA 94105

Commissioner of Patents and Trademarks

Washington, D. C. 20231

Sir:

I, Bertram I. Rowland, attorney for applicant in the subject application, do hereby declare as follows:

On December 19, 1980, I received a letter from the Office of the Board of Patents of the University of California, with an enclosure, requesting me to provide an opinion on the patentability of the subject invention. Such an opinion was provided and on January 7, 1981, I was authorized to begin preparation of the application. After discussions with the inventor, who was a Professor at the University of California, Riverside, on February 5, 1981, a disclosure was provided me for preparing the application. On February 24, 1981, a proposed application was forwarded to the inventor, requesting him to review the application, execute it if appropriate, return the executed application to me and to deposit the cell line at the A.T.C.C. The inventor promptly executed the application but withheld returning the application to me and requested his technician to grow up the cells so that they might be deposited.

On March 23, 1981, I forwarded the application to my associate in Arlington, Virginia and requested her to file the application upon my authorization, when I confirmed that the cell line had been deposited at the A.T.C.C. On or about March 26, 1981, I was informed by Dr. Lundak that the cell line had been forwarded to the A.T.C.C.and I notified my associate to file the application. In fact, the cell line had not been deposited and Dr. Lundak was under a misapprehension that the cell line had been forwarded. I became aware of this contretemps when I was informed by Ms. Brandon at the A.T.C.C., that I letter I had sent to her indicating that she had possession of the subject cell line was confusing, since she was unaware of such cell line. I promptly called Dr. Lundak and informed him of the situation. He investigated and found that in fact the cell line had not been sent and promptly corrected the situation.

The undersigned declarant further declares that all statements made herein of his knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 5/5/82

Bertram I. Rowland

BIR/gs

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| In re application of | |
| Robert L. Lundak | Examiner: J. Tarcza |
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San Francisco, CA 94105

Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

I, Robert L. Lundak, hereby declare as follows:

I am the sole inventor of the above-referenced application and developed the WI-L2-729-$HF_2$ hybridoma cell line which is described and claimed in said application.

On March 26, 1981, the filing date of the subject application, and at all times thereafter, the WI-L2-729-$HF_2$ hybridoma cell line was stored at the University of California, Riverside, at three separate locations, including my own laboratory, the laboratory of Dr. Bruce Devens, and the laboratory of Dr. Richard Lubin. Multiple ampules of the cell line were stored in liquid nitrogen at each location. The purpose of the separate storage at different locations was to assure the permanent maintenance of the cell line and to protect against accidental loss.

The cell line was also stored at the laboratory of Dr. John Lewis at the Loma Linda University Medical Center, Loma Linda, California. The cell line was released to Dr. Lewis in order to allow him to characterize the cell line. Dr. Lewis has since maintained the cell line as further protection against its loss.

At all times since March 26, 1981, the filing date herein, the subject WI-L2-729-$HF_2$ cell line has been maintained by me, and by others on my behalf, with all necessary precautions taken to assure its permanence and availability.

The undersigned declarant declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 3/23/83

By: Robert L. Lundak
Robert L. Lundak